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Docket No. DOC 0057 PA/DC5074/GC792-4

### REMARKS

The Office Action dated July 21, 2005 has been carefully considered. Accordingly, the arguments and remarks presented herein are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

Applicants acknowledge the acceptance of the formal drawings filed on April 27, 2005.

By the present Amendment, the Specification has been amended to comport with the Cooperative Research and Technology Act of 2004. Rules implementing the provisions of this Act went into effect on September 14, 2005. 35 USC §103(c)(2)(C) now requires that the specification disclose the names of the parties to any joint research agreement under which the invention was developed to take advantage of the provisions of the CREATE Act. As this change does not involve the addition of new matter, entry is believed to be in order and is therefore respectfully requested.

Applicants request reconsideration of the Examiner's improper shift in election of a new species and consequent shift in the claims under examination. The basis for this request is set forth in detail, below.

Further, in order to vitiate the need to file a formal Petition under §1.181, Applicants also request reconsideration of the finality of the rejections in the July 21 Office Action. The basis for this request is set forth in detail, below.

Claims 1-33 are currently pending in the application. The Examiner asserts that claims 1-4, 8, 9, 12-15, and 31 are subject to examination.

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#### **Improper Examiner's Election**

In a section of the prior January 25, 2005, Office Action designated "Examiner Elected Species" (page 3) the Examiner noted that he extended a search to a peptide sequence disclosed by the allegedly anticipatory reference he was asserting, Coleman, and subsequently withdrew claims 4-9, 12-14 and 31 from further consideration. In addition, the Examiner withdrew claims 10 and 11 as not reading on the elected species, there being no other allowable linking claim. Hence, the Examiner narrowed the examination to three claims: 1; 3; and 15. After an apparently successful traversal by Applicants of the rejection asserted on the basis of the Coleman reference, the Examiner has, in this office action, shifted his election to a different peptide sequence, and examined a different set of claims. This is an improper Examiner's election under 37 CFR 1.142, and 37 CFR 1.143, second sentence, which stipulates that the Examiner will not make the election for the applicant, and under MPEP § 818.01 which notes that an election becomes fixed when the claims in an application have received an action on their merits by the Office.

Applicants therefore respectfully request rejoinder and examination of claims 5-7, 10, 11, 32 and 33.

#### **Improper Final Rejection**

Applicants respectfully submit that the Examiner's present assertion of a new ground of rejection was not mandated by Applicants' prior amendment and that issuance of a final rejection in this Office Action is therefore unwarranted and premature. Applicants submit that the Examiner's improper election of a new peptide species for examination, combined with his assertion of an irrelevant reference directed to vaccines in the first action on the merits, resulted in the need for the Examiner to find another basis for rejection of the present claims.

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In the previous Amendment in response to the January 25, 2005 Office Action, Applicants amended independent claim 1 to incorporate the recitation of original claim 3, and to clarify that claim 1 is directed to personal care compositions. Other minor amendments to the claims were for purposes of clarification or to correct dependency. The prior amendment made by Applicants did not add or delete any substantive matter that was not already in claims under examination at that time. A perusal of the issue in MPEP §706.07 (premature finality is not permitted to be the subject of an appeal and therefore published as authority, but is reviewable by Petition in the event a request for reconsideration is denied) indicates that a final rejection is rarely appropriate when the amendments to the claims entirely comprise a shifting of limitations from dependent to independent claims, as opposed to the introduction of a new limitation to the claims under examination in their entirety.

Further, in the previous Amendment, Applicants submitted traversals and remarks based on claims 1, 3 and 15 that the Examiner had set forth as the elected claims under examination. The Examiner has shifted the election in this office action and examined different claims, some for the first time. By making this rejection final, Applicants are faced with a situation where they are being forced to pay an additional application filing fee in order to have the opportunity to respond to a first examination on the merits of many of the original pending claims, in contraindication to MPEP §706.07(a) and standard USPTO prosecution practice.

In summary, Applicants respectfully submit that the new ground asserted by the Examiner in this office action was necessitated by (1) the Examiner's original assertion of an irrelevant reference, which resulted in an unwarranted action withdrawing many of the pending claims (Applicants properly traversed this first Examiner's election and requested rejoinder in the prior office action), and (2) the current improper Examiner's election which shifted the

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claims under examination, including claims not in the Examiner's first election, and including claims not elected prior to the first office action.

Since the Examiner is asserting new references and a new ground of rejection in this Office Action which were not necessitated by Applicants' prior Amendment, it is improper under MPEP §706.07(a) to designate this rejection as final. Hence, Applicants respectfully request reconsideration and withdrawal of the designation of the present rejections as "final" as permitted in MPEP §706.07(d).

### **35 USC §102**

Claims 1-4, 8, 9, 12-14, and 31 were rejected under 35 USC §102(b) as being anticipated by published U.S. Patent Application 2002/0147154 to Wolfinbarger, J.R., in view of Voet, D. and Voet, J.G. Biochemistry, 2nd Ed. (1995). Specifically, the Examiner notes that Voet teaches that collagen comprises the sequence GL- [H<sub>1</sub>G<sub>1</sub>P<sub>1</sub>I<sub>1</sub>G<sub>2</sub>H<sub>2</sub>P<sub>2</sub>R<sub>1</sub>G<sub>3</sub>R<sub>2</sub>T<sub>1</sub>G<sub>4</sub>D<sub>1</sub>(A<sub>1</sub>G<sub>5</sub>P<sub>3</sub>)<sub>2</sub>(H<sub>2</sub>G<sub>6</sub>P<sub>4</sub>)<sub>4</sub>]P<sub>5</sub>, which the Examiner asserts to be encompassed by the repeat sequence protein polymer formula recited in claim 1. The Examiner asserts that the first reference, Wolfinbarger, teaches a cosmetic composition comprising marine invertebrate type V telopeptide containing collagen in particularly disclosed weight percentages. This rejection is traversed and reconsideration is respectfully requested.

First, Applicants note that the Examiner has atypically asserted a combination of references in the allegedly anticipatory rejection. In order for this to be proper, the Examiner must be using the second reference merely to define or enable the relevant disclosure of the first reference. "The Federal Circuit regards it as hornbook law that anticipation must be found in a single reference, device or process" Harmon, R.L. Patents and the Federal Circuit, Fifth Ed.

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(2001), page 91, citing *Studiengesellschaft Kohle v. Dart Indus., Inc.*, 726 F.2d 724, 220 USPQ 841 (Fed. Cir. 1984). Additional references may only be used if the purpose of the second reference is "to shed light on what it [the allegedly anticipating reference] would have meant to those skilled in the art at the time." *Id.* Hence, Applicants will proceed to traverse this rejection accordingly.

Instant claim 1 is directed to a personal care composition comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient. The repeat sequence protein polymer formula comprises:  $T_y[(A_n)_x(B)_b(A'^{n'})_x(B'')_b(A''^{n''})_{x''}]_iT'y'$  wherein: T and T' each comprise an amino acid sequence of from about 1 to about 100 amino acids, wherein the amino acid sequence of T' is the same as or different from the amino acid sequence of T; y and y' are each an integer from 0 to 1, wherein the integer of y' is the same as or different from the integer of y; A, A' and A'' are each individual repeating sequence units comprising from about 3 to about 30 amino acids, wherein the amino acid sequence of A' and the amino acid sequence of A'' are the same as or different from the amino acid sequence of A; n, n', and n'' are integers of at least 2 and not more than 250; x, x' and x'' are each 0 or an integer of at least 1, wherein each integer varies to provide for at least 30 amino acids in the A, A' and A'' individual repeating sequence units, and wherein the integer of x' and the integer of x'' are the same as or different from the integer of x; B and B' each comprise an amino acid sequence of from about 4 to about 50 amino acids, wherein the amino sequence of B' is the same as or different from the amino acid sequence of B; b and b' are each an integer from 0 to 3, wherein the integer of b' is the same as or different from the integer of b; i is an integer from 1 to 100. The personal care composition is adapted to provide at least one benefit to the surface to which the personal care composition is applied.

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Applicants submit that the Examiner has misconstrued the formula recited as defining the repeat protein polymers of claim 1 and that the peptide sequence set forth in Voet does not meet the recited formula.

The Examiner correctly identifies the peptide sequence of Voet illustrated in figure 7-30, once re-coded into the single amino acid designator convention, as disclosing the following:

...GL [HGPIGHGPRGRTGD(AGP)2(HGP)4]-P...

The Examiner then asserts that all the amino acids through GL correspond to the recited T, and all the amino acids from P through some indeterminate amino acid correspond to the recited T', such that y and y' are each equal to 1. Up to this point, Applicants (with a reservation re the Examiner's interpretation as to the permissible lengths of T and T'), substantially agree. However, in contravention to the formula, the Examiner then asserts that the intervening sequence HGPIGHGPRGRTGD, with n =15 corresponds to A<sub>n</sub>. However, the formula and specification clearly teach that A is a repeat sequence unit having a length of 3-30 amino acids, with n indicating the number of times that unit repeats, n being at least 2. Here, there is no unit in the Voet peptide that could be "A", repeating 15 times. While A is permitted, under the present formula, to be a 15-residue long peptide sequence, it still must repeat at least twice, since "n" must be at least 2. The sequence identified as A by the Examiner is merely 15 various amino acids that do not repeat.

Assuming arguendo, however, that the Examiner concedes this obvious point and simply adds this 15-residue sequence to T, thereby making A=AGP, n=2 and A'=HGP, n=4, Applicants submit that the Voet sequence still is not encompassed by the recited formula. This manipulation yields an 18-residue sequence that does not meet the requisite limitation "wherein each integer

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varies to provide for *at least 30* amino acids in the A, A' and A" individual repeating sequence units..."

Wolfinbarger fails to disclose any repeat sequence protein polymers according to the formula recited in claim 1. Clearly, under proper application of §102, the Examiner's attempt to use Voet to define the "collagen" of Wolfinbarger, fails to bring this collagen within the scope of claim 1.

Anticipation under 35 USC §102(b) requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 USPQ2d 1337, 1341 (Fed. Cir. 1986). The corollary of the rule is that absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 230 USPQ 81 (Fed.Cir. 1986). Wolfinbarger fails to teach or suggest a personal care composition comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient wherein the repeat sequence protein polymer formula comprises the formula recited in claim 1. The second reference, Voet, asserted to define the collagen of Wolfinbarger, actually defines a collagen outside the scope of the present independent claim.

For these reasons, Applicants submit that Wolfinbarger, in view of Voet, does not anticipate independent claim 1, or claims 2-4, 8, 9, 12-14, and 31, that depend therefrom. Hence, the rejection of instant claims 1-4, 8, 9, 12-14, and 31 under 35 USC §102 over Wolfinbarger, in view of Voet, is overcome and reconsideration is respectfully requested.

Regardless of the outcome of the requests with respect to the improper election and premature finality, it is believed that the above represents a complete and effective response to

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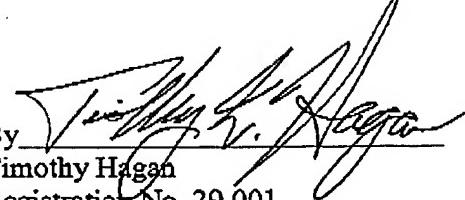
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the rejection under 35 USC §102 and places the present application in condition for allowance.

Reconsideration and an early allowance are requested.

Respectfully submitted,

By   
Timothy Hagan  
Registration No. 29,001

One Dayton Centre  
One South Main Street, Suite 1300  
Dayton, Ohio 45402-2023  
Telephone: (937) 449-6400  
Facsimile: (937) 449-6405  
e-mail:timothy.hagan@dinslaw.com

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